

National Patterns of Potentially Inappropriate Drug Use in the US Elderly: An Evaluation of the CMS Enclave as a Scalable Population Assessment Tool

Mallika L. Mundkur, MD¹, Fabrício S. P. Kury, MD², Ferdinand Dhombres, MD, PhD²,
Vojtech Huser, MD, PhD², Olivier Bodenreider, MD, PhD²

¹ Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's
Hospital, Harvard Medical School, Boston, MA

² Lister Hill National Center for Biomedical Communications, National Library of
Medicine, National Institutes of Health, Bethesda, MD

I. Introduction

According to recent estimates from the Centers for Disease Control (CDC), 90% of adults 65 and older report taking at least one prescription drug— 38% of these individuals report taking five or more such drugs simultaneously (CDC website, accessed 3/9/2016). To minimize risks of inappropriate prescribing among the elderly, the American Geriatric society releases period guidelines regarding potentially inappropriate medications (PIMs), i.e., drugs to be avoided in this age group [1]. Medicare prescription drug claims represent a viable and underexplored alternative data source for monitoring use patterns of PIMs in the elderly. Two studies have explored and demonstrated the utility of Part D claims for surveillance of PIM utilization [2, 3]. However, neither has explored how such assessments could be scaled either in size (e.g., to 100% of the Medicare population), or efficiency (e.g., real-time analysis, or distinct assessments occurring simultaneously).

One tool that could potentially be used to scale population assessments of PIM use is the relatively new CMS enclave or “Virtual Research Data Center” (CMS Press Release; Nov., 2013). However, it has not been formally evaluated yet and collective experience with this tool remains limited. Traditional access to Medicare claims data was typically restricted to a relatively small portion of the Medicare the population. In contrast, the enclave provides approved individuals with access to all available years of data, on up to 100% of the total Medicare population for a fixed cost through a cloud-based remote server.

The objective of this investigation is to characterize recent national patterns of inappropriate prescribing among the US elderly. Compared to previous studies, we analyze the largest sample of Medicare beneficiaries available to date and more recent prescription drug claims. Finally, this work contributes to identifying the characteristics of the CMS enclave that could facilitate or impede its ability to scale assessments of the population.

II. Materials and methods

Data request/access. We requested a 5% sample of patients 65 and older who were continuously enrolled in a Medicare Part D plan during the year 2009. All data were requested through CMS/ResDAC and the project was conducted under the terms of a CMS-approved data use agreement (DUA). Data were accessed and analyzed entirely within the enclave using SAS Enterprise Guide and aggregate reports were downloaded from the enclave in accordance with the DUA. **Medication list.** We restricted our analysis of medication use to only those drugs listed as potentially inappropriate in the 2012 American Geriatric Society guidelines, the most recent set of guidelines available at the time the study was conducted. From this list of 136 drugs, only drugs with strong evidence, as indicated by the guideline, were evaluated. We excluded drugs for which the recommendation to avoid prescribing was conditional to specific daily doses or prescription regimens (e.g., sliding scale insulin therapy). The final list contains 128 drugs. **Aggregation of NDC codes.** National Drug Codes (NDCs) represent unique numeric identifiers for each drug and specify not only ingredient and dose but also formulation and packaging. Individual prescriptions are identified by the NDC code, though for the purpose of our analysis, we grouped drugs at the ingredient level using a previously described RxNorm-based mapping algorithm developed by one of our authors [4]. **Primary outcome.** For each drug in our list of PIMs, the primary outcome of interest was unadjusted prevalent drug use—the numerator of this value being the number of individuals in our cohort receiving at least one prescription for a PIM during 2009, the denominator being the total number of patients in the cohort (including those who may not have received any prescriptions during the year). We analyzed prevalent drug use for the population overall, and stratified by age.

III. Results

Our final cohort included 1,018,943 adults 65 and older—49% were 65-74, 36% were 75-84, and the remaining 15% 85 and above. Within our cohort, 47% of all individuals received at least one prescription for a medication from our final list of 128 medications. The top 5 PIMs most frequently utilized in our cohort were *zolpidem* (6.3%), *nitrofurantoin* (4.5%), *meloxicam* (4.5%), *ibuprofen* (4.4%), and *cyclobenzaprine* (4.0%). Generally, it appeared that PIMs were prescribed less often to older patients than younger patients, with the exceptions of *quetiapine* and *nitrofurantoin*, which were prescribed at a higher rates among patients 95 and older (9.2% and 4.8%, respectively), compared with all other age groups.

IV. Discussion

Significance. Our study represents the largest and most recent claims-based evaluation of national utilization patterns of potentially inappropriate medications, and is only the third such study using claims from Medicare Part D. Further, ours is the only study to date specifically exploring use of the CMS enclave as a potential tool to scale population assessments.

Findings. Our findings are consistent with those reported in previous studies. Zhang and colleagues [3] evaluated geographic variation in inappropriate prescribing according to a distinct but overlapping list of medications specified by the Healthcare Effectiveness Data and Information Set (HEDIS) measures in a national sample of 533,170 Medicare beneficiaries during the year 2007. While they did not report on individual drugs, they reported that across the geographic referral regions evaluated, 24.9% of older adults were taking at least one high-risk medication. Holmes et al. [2] evaluated prescriber and patient characteristics relating to PIM use in a Texas-only cohort of 677, 580 fee-for-service Medicare beneficiaries during the year 2007; in this cohort, 31% of individuals had been exposed to a drug on the 2003 Beers list. Our estimates of overall PIM utilization were substantially higher than either of these studies (47%), which is not surprising given that our medication list was derived from a more recent and expanded list of medications than those used in the prior studies. Of the drugs reported in the Texas-based study, the top 5 PIMs identified were *propoxyphene* (12%), *nitrofurantoin* (5.5%), *clonidine* (4.2%), *cyclobenzaprine* (4.1%) and *amitriptyline* (3%). The corresponding estimates from our cohort were *nitrofurantoin* (4.5%), *clonidine* (2.8%), and *amitriptyline* (2.2%); *propoxyphene* was not included in our study, because it had been excluded from the 2012 Beers list given its removal from the market.

Suitability of the CMS enclave. Our team found the CMS enclave data-sharing platform to be conducive to scaling of population assessments in terms of size though not in terms of efficiency. Our cohort was only 1 million patients in size, however, the virtual environment is equipped to store and process much larger datasets. We identified two efficiency-related issues that greatly limit CMS enclave for population assessment. First, only one program could be run at any given time within the SAS application available within the enclave; second, claims data still must be approved through the pathway of ResDAC/CMS, a process typically entailing several months, thus precluding assessment of the most recently generated claims.

Conclusions. Our study provides a recent and accurate snapshot of national patterns of drug utilization among the US elderly. We found that nearly half of elderly Americans receive a medication for which there is evidence of risk. In addition, we are among the first to report on the strengths and weaknesses of the CMS enclave for population-wide assessments. Future work will include more complex analyses within the enclave such as prevalence of drug-drug combinations.

Acknowledgments

This work was supported by the Intramural Research Program of the NIH, National Library of Medicine. The authors want to thank Dr. Clem McDonald for his guidance at early stages of this project.

References

1. By the American Geriatrics Society Beers Criteria Update Expert P. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015;63(11):2227-46.
2. Holmes HM, Luo R, Kuo YF, Baillargeon J, Goodwin JS. Association of potentially inappropriate medication use with patient and prescriber characteristics in Medicare Part D. *Pharmacoepidemiol Drug Saf* 2013;22(7):728-34.
3. Zhang Y, Baicker K, Newhouse JP. Geographic variation in the quality of prescribing. *N Engl J Med* 2010;363(21):1985-8.
4. Peters LB, Bodenreider O. Approaches to supporting the analysis of historical medication datasets with RxNorm. *AMIA Annu Symp Proc* 2015:1034-1041.